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| 10/509,137 | 09/27/2004 | Jeffrey S Lockwood | 7175-71858 | 1944 |
| 23643 7590 06/22/2007 BARNES & THORNBURG LLP 11 SOUTH MERIDIAN INDIANAPOLIS, IN 46204 | | | EXAMINER REICHLE, KARIN M | |
| | | | ART UNIT 3761 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,137

Applicant(s)

LOCKWOOD ET AL.

Examiner

Karin M. Reichle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>4/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b)**. Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Specification

Drawings

2. The drawings were received on 4-9-07. These drawings are not approved. The proposed Figure 3 now shows the arrow 22 denoting the wound layer not the cover and the openings 64 in the cover. 22 and the lines therefrom are denoted by dashed lines, not solid lines.

3. The drawings are objected to because in Figure 3, a top plan view, the lines from 31, 30, 46, and 32 and the structure underlying the cover layer 20 should also be shown with dashed lines to denote underlying structure. The rightmost occurrences 64 should be 46 instead. Note discussion in preceding paragraph also Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number

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of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Description

4. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: the paragraph at page 5, line 22, first line, the paragraph at page 6, line 30, second to last line, page 7, lines 9, 20 and 22, i.e. "connector" should be --connector--.

5. The disclosure is objected to because of the following informalities: In claims 1-11 a member which is formed of "non-porous" material is claimed. The remainder of the application also describes a member of "non-porous" material or "non-porous" and non-foam-like.

Applicants have not explicitly defined "non-porous" but "porous" is defined as "having or full of pores" and "pore" is defined as "a minute orifice" or "minute surface opening or passageway" by

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the dictionary, i.e. the usual definition. Therefore a “non-porous” member would be one without orifices, surface openings or passageways. However, as described and claimed the member 19, i.e. 20 and 22, appear to be “porous” because it/they include orifices, surface openings or passageways and thereby the description of the member appears to be inconsistent. In the 4-9-07 response Applicant sets forth that pores are “very small: INFINITESIMAL” orifices, openings or passageways as compared to the claimed “discrete” holes or openings. However, the terminology “very small, infinitesimal” is considered relative absent specific dimensions thereof and the disclosed dimensions of the “discrete” holes or openings, e.g. at page 19-27, are relatively “very small, infinitesimal”. Therefore, a clear consistent description of the member still needs to be set forth. Note paragraphs 6 and 7 *infra*.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 2, is the top surface of claim 1 and the cover of claim 2 one and the same, i.e. at a minimum how many communications, e.g. openings, are required. Note claim 10. With regard to claims 1-11 see the discussion of the terminology “non-porous” in paragraph 5 *supra*, i.e. it is unclear whether the member is “non-porous” or not.

Claim Language Interpretation

7. Due to the lack of clarity discussed in paragraph 6 supra, claim 2 will be interpreted as requiring the cover layer to at least in part define the top surface of claim 1. Due to the lack of clarity discussed in paragraphs 5 and 6 supra, claims 1-11 will be interpreted as requiring a member of non-foam-like and non absorptive material absent claiming specific dimensions of the openings, holes, etc.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heaton '127 in view of Zamierowski PCT '795.

Claim 1: See '127 at Figures 5-9c, page 2, first full paragraph, page 3, second to last line-page 4, fifth to last line, and page 7, line 12-page 9, last line: the member is 30 and 73, the top surface is the top surface of 30 and the top surface of 73 extending beyond 30, the bottom surface is the bottom surface of 73, the "discrete" holes are the openings of the cells of open celled foam 73 at the bottom surface thereof, the at least one "discrete" opening is the opening of the cells of 73 at the top surface thereof beyond 30 or the openings at the periphery of 30 defined between projections 32, see Figures 5-7, the port is at least 36 which is configured to communicate with the vacuum source and in fluid communication with each "discrete" hole and the at least one "discrete" opening. With regard to lines 3-4 of claim 1 attention is again directed to page 4, lines 10-12. See also the response to Arguments section infra.

Claim 1 now also claims the member formed from a material that is generally “non-porous”, generally non-foam-like and generally non-absorptive. However, as best understood, see discussion in paragraphs 5-7 supra, the layer 73 of ‘127 is, i.e., foam-like to and some extent hydrophilic. See the paragraph on page 4, starting at line 17 of ‘127. See also ‘795 at Figures 9 and 10 and page 18, line 20-page 21, line 3, i.e. a member for use in a vacuum bandage includes a wound contacting layer which can polyurethane foam or mesh/sheet of synthetic material which is generally nonabsorbent or a hydrophilic colloid material. Therefore, to make the polyurethane foam layer of ‘127, i.e. a generally foam-like, absorptive material, as best understood, a mesh/sheet of synthetic material which is generally nonabsorbent and non-foam like instead, as best understood, would be obvious to one of ordinary skill in the art in view of the interchangeability as taught by ‘795. It is noted that “mesh “ is defined as “any of the open spaces in a cord, thread or wire network, the cords, threads or wires surrounding these spaces, a net or network” and “net” is defined as “an openwork fabric made of threads, cords or ropes that are woven or knotted together at regular intervals” and “network” is defined as “something resembling a net consisting of a number of parts, passages, lines or routes that cross, branch out or interconnect”. Therefore, a member 73 of such material would also include “discrete” holes or openings at the bottom surface thereof, at least one “discrete” opening at the top surface thereof beyond 30 or openings at the periphery of 30 defined between projections 32. Therefore, the member of the prior art would be of material as claimed, as best understood, especially in light of the lack of claiming of specific dimensions of such “discrete” holes and openings.

Claim 2: The wound contacting layer is 73 and includes a bottom surface adapted to be in contact with and generally conform to the wound surface, see portions of ‘127 cited, especially

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page 4, lines 10-12 and thereby, by incorporation, '873, at, e.g., Figure 10 and the paragraph bridging pages 8-9, i.e. clearly teaches the wound contact layer of a wound cover packed into the recesses of the wound cavity, the channels of the upper surface are formed by the spaces/passages in the mesh/sheet of material, the cover is 30 which is coupled to, e.g. by the layer 20, and engages the upper surface to the wound contacting layer, and which cover cooperates with the channels/spaces/passages of layer 73 to define passageways 33 between the port and each of the holes and the port and the at least one opening.

Claim 3: See Figure 7, i.e. a surface area of the cover is smaller than a surface area of the layer 73 so that the channels/spaces/passages of layer 73 extending beyond an outer edge of cover 30 define a plurality of the "discrete" openings, i.e. the spaces/passages of 73 at the top surface thereof laterally beyond 30 discussed supra with respect to claim 1.

Claim 4: The cover includes a plurality of "discrete" openings, i.e. the openings at the periphery of 30 defined between projections 32 as discussed supra with respect to claim 1, which communicate with the channels of the layer, see discuss of claims 1-3 supra, to define a plurality of the "discrete" openings.

Claim 5: See the discussion of claims 1, 3 and 4.

Claim 6: See the discussion of the claims supra as well as '873 again, e.g. Figure 10 and the paragraph bridging pages 8-9 clearly teaches a wound contact layer of a wound cover, i.e. an opening thereof, packed into the recesses of the wound cavity, i.e. positioned to/having the capability to engage with an undermined portion of the wound.

Claim 7: The terminology "relative thin and flexible" is considered relative absent the claiming of specific dimensions of thinness and flexibility. See also '127 at the portions cited

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with respect to claim 1, e.g. layer 73 is described as "relatively thin" and "flexible" and extends beyond 30, i.e. defines peripheral portions of the member. Therefore the member is also considered to be "relatively thin" and "flexible".

Claim 8: See the discussion of claims supra. It is noted that this claim only sets forth that the surface areas relationship functions to permit communication with the undermined portion.

Claims 9-11: See the discussion of claims supra. It is noted that these claims only require the second plurality of "discrete" holes be adapted/function to communicate with the undermined portion.

Response to Arguments

10. Applicant's remarks have been considered but are either deemed moot in that the issue has not been reraised or deemed not persuasive for the reasons set forth supra. Specifically Applicant's remarks are narrower than the claim language as best determinable and/or the teachings of the prior art, e.g. incorporated '873, e.g. Figure 10, and the paragraph bridging pages 8-9 clearly teaches a wound contact layer of a wound cover, i.e. an opening thereof, packed into the recesses of the wound cavity, i.e. positioned to engage or adapted to communicate, e.g. fluidically, with an undermined portion of the wound.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any new grounds of rejection were necessitated by the amendments to claims 1-2, 6 and 8 and the cancellation of claim 12.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Karin M. Reichle
Primary Examiner
Art Unit 3761

KMR
June 19, 2007